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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,315	03/03/2004	Robert C. O'Brien	31611.0031	4362

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WILSON GREATBATCH TECHNOLOGIES, INC.
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CLARENCE, NY 14031

EXAMINER

HELLER, TAMMIE K

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,315

Applicant(s)

O'BRIEN, ROBERT C.

Examiner

Tammie Heller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>30 July 2004</u> ; <u>3/3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Specifically, US Patent application number 10/719,632 on the last line of page 8 was incorporated into the specification but absent from the information disclosure statement.

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show appropriate detail as described in the specification. Specifically, Figures 8-12, which are black and white photographs depicting experimental polarization results. From these photographs, it is difficult to identify any important structural characteristics of the surface coatings. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be

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canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7 and 11-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 22 of copending Application No. 10/719,632. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the copending application can be applied to carbon-containing outer coating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 22 of copending Application No. 10/719,632 in view of Malonek et al. (U.S. Patent No. 6,293,704). The copending application discloses the invention substantially as claimed except the surface area of the substrate was not increased by any of the methods including sinter processing, micromachining, grit blasting, and chemical etching. However, Malonek et al. teaches of the use of heat treatment, sandblasting, and oxidation on the substrate (see col. 9, ln. 11-15) to increase the surface area of the substrate. Therefore, it would have been obvious to one having ordinary skill in the art to modify the electrode disclosed in the copending application by treating the substrate with heat, sandblasting, or oxidation in order to increase the effective surface area of the substrate.

This is a provisional obviousness-type double patenting rejection.

6. Claims 9-10 and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 22 of copending Application No. 10/719,632 in view of Frericks et al. (U.S. 2004/0127966). The copending application discloses the invention essentially as claimed except it remains silent as to the thickness of the intermediate and carbon-containing coatings. However, Frericks et al. discloses a stimulation electrode with an intermediate ceramic coating layer, which has a thickness of 1 nm to 20 μm , and an oxidation protection coating layer, which has a thickness of 500 nm to 5 μm (see paragraphs 17 and 18). The oxidation protection layer is formed of an oxide, a carbide, a nitride, or a polymer, and therefore serves as a "carbon-containing coating adhered to the intermediate coating" as in claim 1 of the present invention (see paragraph 16, In. 5). Frericks teaches that the prescribed thicknesses for the ceramic and oxidation protection layers are optimally chosen such that they offer sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of the copending application with those of Frericks et al. It would have been obvious to modify the intermediate and carbon-containing coatings on the electrode of the copending application to have the thicknesses prescribed by Frericks et al. in order to provide the electrode with sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 7-8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Malonek et al. Malonek et al. teaches implantable high capacitance electrodes, the substrate of which includes a "material selected from the group of platinum, platinum-iridium, titanium, and carbon" (see col. 3, ln. 65-67). Malonek et al. further teaches a coating which is chosen from the group of iridium oxide, titanium nitride, pyrolytic carbon and activated carbon (see col. 4, ln. 3-5), each of which is biocompatible and electrically conductive. Additionally, Malonek et al. teaches of the use of metal oxides and metal nitrides in particle coatings (see col. 1, ln. 61-62). Malonek et al. further teaches of the

use of heat treatment, sandblasting, and oxidation on the substrate (see col. 9, ln. 11-15). Regarding claim 11, Malonek et al. teaches the use of titanium nitride as a coating for the substrate (see col. 9, ln. 38).

9. Claims 1-7 and 11-15 are rejected under 35 U.S.C. 102(e1) as being clearly anticipated by O'Brien et al. (U.S. 2005/0075708). O'Brien et al. discloses an implantable electrode comprising a substrate, an intermediate coating, and a carbon-containing coating adhered to the intermediate coating (see claim 1, page 3). It is disclosed that the substrate of O'Brien et al. is selected from the group consisting of tantalum, titanium, zirconium, iridium, platinum and niobium (see claim 2, page 3). O'Brien et al. further discloses that the intermediate coating is selected from a group consisting of a nitride, carbide, carbonitride, and oxide of the group of tantalum, titanium, zirconium, iridium, platinum, and niobium (see claim 5, page 3). Furthermore, the carbon-containing coating material of O'Brien et al. is selected from the group consisting of nitrogen-doped carbon wherein the nitrogen concentration is of "about 1 ppm to about 57 atomic percent" (see claims 2-3, page 3). Additionally, O'Brien et al. discloses a sputtering method of depositing the carbon-containing layer onto the substrate (see claim 22, page 4).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. in view of Malonek et al. O'Brien et al. discloses the invention substantially as claimed except the surface area of the substrate was not increased by any of the methods including sinter processing, micromachining, grit blasting, and chemical etching. However, Malonek et al. teaches of the use of heat treatment, sandblasting, and oxidation on the substrate (see col. 9, ln. 11-15) to increase the surface area of the substrate. Therefore, it would have been obvious to one having ordinary skill in the art to modify the electrode of O'Brien by treating the substrate with heat, sandblasting, or oxidation in order to increase the effective surface area of the substrate.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malonek et al. and O'Brien et al. in view of Frericks et al. While Malonek et al. and O'Brien et al. disclose a carbon-containing coating adhered to an intermediate coating which is supported on the substrate, both remain silent as to the required thickness for

each of these two coatings. Frericks et al. discloses a stimulation electrode with an intermediate ceramic coating layer, which has a thickness of 1 nm to 20 μm , and an oxidation protection coating layer, which has a thickness of 500 nm to 5 μm (see paragraphs 17 and 18). The oxidation protection layer is formed of an oxide, a carbide, a nitride, or a polymer, and therefore serves as a "carbon-containing coating adhered to the intermediate coating" as in claim 1 of the present invention (see paragraph 16, In. 5). Frericks teaches that the prescribed thicknesses for the ceramic and oxidation protection layers are optimally chosen such that they offer sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Malonek et al. and O'Brien et al. with those of Frericks et al. It would have been obvious to modify the intermediate and carbon-containing coatings on the electrodes of Malonek et al. and O'Brien et al. to have the thicknesses prescribed by Frericks et al. in order to provide the electrode with sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

13. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. in view of Frericks. O'Brien et al. discloses the invention essentially as claimed except it remains silent as to the thickness of the intermediate and carbon-containing coatings. However, Frericks et al. discloses a stimulation electrode with an intermediate ceramic coating layer, which has a thickness of 1 nm to 20 μm , and an oxidation protection coating layer, which has a thickness of 500 nm to 5 μm (see paragraphs 17

and 18). The oxidation protection layer is formed of an oxide, a carbide, a nitride, or a polymer, and therefore serves as a "carbon-containing coating adhered to the intermediate coating" as in claim 1 of the present invention (see paragraph 16, ln. 5). Frericks teaches that the prescribed thicknesses for the ceramic and oxidation protection layers are optimally chosen such that they offer sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of O'Brien et al. with those of Frericks et al. It would have been obvious to modify the intermediate and carbon-containing coatings on the electrode of O'Brien et al. to have the thicknesses prescribed by Frericks et al. in order to provide the electrode with sufficient oxidation protection while not substantially affecting the surface structure of the substrate.

14. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malonek et al. in view of Frericks et al. as applied to claims 9 and 10 above, and further in view of Edeling et al. (U.S. Patent No. 4,612,100) and Schaldach et al. (Biomed. Technik 34(1989), 185-190. Pacemaker electrodes made of titanium nitride"). Edeling et al. teaches of a method for the fabrication of an implantable electrode comprising a substrate with a layer of carbon sputtered from a target onto at least a portion of the outer surface of the electrode body portion (see col. 2, ln. 36-42). While Frericks et al. discloses that the carbon-containing coating may be deposited on the surface of the intermediate coating using a laser (see paragraph 3, ln. 4-5), the method of sputtering is not mentioned. Sputtering is a preferred method by which a thin metallic film may be

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deposited on the surface of a given substrate. As disclosed by Schaldach et al. in the disclosed prior art, "Pacemaker Electrodes Made of Titanium Nitride," sputter-deposited electrode coatings create a micro-crystalline surface structure, which makes these coatings superior to other coatings contained in the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ a sputtering method as taught by Edeling et al. and Schaldach et al. to deposit the carbon-containing coating onto the intermediate layer of Malonek et al. in order to ensure that the coating is of the appropriate thickness as previously discussed.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bussard et al. (U.S. Patent No. 4,440,178), Robblee (U.S. Patent No. 4,677,989), Dahl et al. (U.S. Patent No. 5,074,313), Munshi et al. (U.S. Patent No. 5,683,443), Gelb et al. (U.S. Patent No. 6,799,076), and Frericks et al. (U.S. Patent No. 6,901,297).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on M-F 7-4:30, alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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